



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/697,590

10/27/2000

Judith Fitzpatrick

018792/0177

3507

22428

7590

06/05/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

TURNER, SHARON L

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,590

Applicant(s)

FITZPATRICK ET AL.

Examiner

Sharon L. Turner

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 55 and 59-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

R sponse to Amendment

1. The amendment filed 3-15-06 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn.
4. Claims 55 and 59-60 are pending and are under Examination.

Claim Objections

5. Claim 59 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 59 is objected to because it does not properly fall within the scope of the base claim. Claim 55 stipulates in (b) that there must be an additional amino acid before and after the HARL portion. Accordingly, the dependent claim cannot consist of the peptide HARL as the peptide is required to have additional amino acids before and after.
6. The scope of claim 55 is limited to peptides not exceeding 25 amino acids in length. This is in contrast to the scope of claim 60 that reads on full length NTP as encompassed by the comprising language, particularly, "comprising a fragment."

Rejections Maintained and Necessitated by Amendment

Doubl Pat nting

Art Unit: 1649

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 55 and 59-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending Application No. 10/146,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is similarly drawn to isolated neural thread protein (NTP) peptides corresponding to species of HARL sequences, with additional NTP residues and which are deemed to inherently bind to themselves based upon the presence of the NTP sequence, known and evidenced to bind to itself as disclosed in the art, see for example, specification and de la Monte of record below. While the '130 claims are drawn to the peptides provided in a composition of matter claim, patenting of the claim may render obvious instant peptide comprising the same segments of neural thread protein as instantly claimed. The delineated species fall squarely within the boundaries of instant claims and would therefore anticipate the genus of peptides now recited.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants again request in the response of 3-15-06 that the double patenting rejection be addressed when a notice of allowance is issued. No comments as to the correctness of the rejection have been noted.

Applicants arguments filed 3-15-06 have been fully considered but are not persuasive for withdrawal of the rejection. No comments as to the correctness of the rejection are noted. Therefore rejection is maintained as set forth in MPEP 804, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Claim Rejections - 35 USC § 112

9. Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Art Unit: 1649

Claim 59 recites the peptide consisting of HARL. Applicants point to support for the claim amendments within the original claims and pp. 5 and 9. Support is not found for the peptide consisting of only these residues.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 55 and 59-60 are rejected under 35 U.S.C. 102(b and e) as being anticipated by de la Monte et al., US Patent 5,830,670 filed 5-30-1995 and issued 11-3-1998.

de la Monte et al., teach isolated neural thread protein and fragments comprising or having the HARL motif, see in particular SEQ ID NO:120. The peptide is flanked by

Art Unit: 1649

portions of the neural thread protein sequence. Moreover, Monte notes that neural thread protein aggregates and binds to itself, see in particular examples 2-3, 12 and 14-16, particularly in Alzheimer's and Down's syndrome plaques. The full length peptide meets the claim limitations directed to comprising a fragment where the additional amino acids before and after are 100% identical to neural thread protein. Particular fragments and encoding segments are delineated in SEQ ID NO's:1-120. The following excerpts are further noted.

The invention is also directed to the therapeutic use of NTP-derived molecules or fragments thereof to modify or improve dementias of the Alzheimer's type of neuronal degeneration.

Fragment. A "fragment" of a molecule such as NTP is meant to refer to any polypeptide subset of that molecule.

22

Functional Derivative. The term "functional derivatives" is intended to include the "variants," "analogues," or "chemical derivatives" of the molecule. A "variant" of a molecule such as NTP is meant to refer to a naturally occurring molecule substantially similar to either the entire molecule, or a fragment thereof. An "analogue" of a molecule such as NTP is meant to refer to a non-natural molecule substantially similar to either the entire molecule or a fragment thereof.

The above-discussed methods are, therefore, capable of identifying DNA sequences which are code for an NTP or fragments thereof. In order to further characterize such DNA sequences, and in order to produce the recombinant protein, it is desirable to express the proteins which the DNA sequences encode.

This aspect of the invention relates to a method for detecting an NTP or a fragment thereof in a sample

IV. Isolation of NTP

136

The NTP proteins or fragments of this invention may be obtained by expression from recombinant DNA as described above. Alternatively, an NTP may be purified from biological material.

As noted in the patent, particular nucleic acids which encode shorter segments and particular amino acids are set forth in the sequence listing, see in particular SEQ ID NO's:1-121.

Status of Claims

12. No claims are allowed.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1649

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at (571) 272-0867.

Sharon L. Turner, Ph.D.
May 30, 2006



SHARON TURNER, PH.D.
PRIMARY EXAMINER

5-30-06